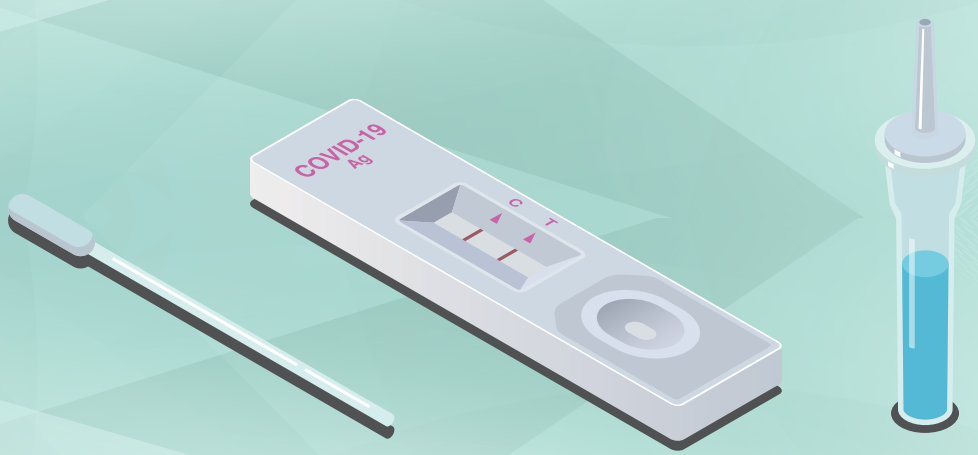
CCC test

新型冠狀病毒抗原檢測試劑

(SARS-Cov-2) Antigen Test Kit

Saliva



自我檢測套裝

CCC

Distributed by Acc Biotect Limited

Website:
www.accbiotech.com

Email:
deepblue@accbiotech.com

Address:
Unit 11D, On Shong Industrial Bldg,
2-16 Wo Liu Hang Rad, Hong Kong

ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.
4th Floor,D-1#Zone, Pearl Industrial Park, 106 Innovation Avenue,
High-Tech Development Zone, 230088 Hefei, Anhui, China

EC REP Luxus Lebenswelt GmbH
Kochstr.1,47877, Willich, Germany

CCC test


CCC test
CE 1434
測試溶液瓶放置孔
新型冠狀病毒抗原檢測試劑（唾液）
COVID-19(SARS-CoV-2)Antigen Test Kit(Colloidal Gold) - Saliva
簡單易用・快速自我檢測・15分鐘即知結果
靈敏度: 96.4% | 特異性: 99.8% | 高精準度
COVID-19
SELF TEST KIT


CCC test
1 Set
新型冠狀病毒抗原檢測試劑（唾液）
COVID-19(SARS-CoV-2)Antigen Test Kit(Colloidal Gold) - Saliva
垂直握住提取管，將2滴樣本加入加樣孔（S）中。
等候15分鐘讀取結果，30分鐘後結果無效。
2×
15 min.
測試劑結果解讀
C T
陽性
陰性
無效
僅供體外診斷使用

紙箱包裝

1件/盒, 500盒/箱

盒尺寸：145 x 65 x 20mm

箱尺寸: 59.5 x 49.5 x 35cm

毛重 18.5kg

包裝盒

說明書

檢測裝置

提取管1　　提取管2

提取試劑的抗原提取管

消毒棉棒

收集袋

測試套裝包含：

包裝盒/說明書/檢測裝置

含0.4ml提取試劑的抗原提取管（提取管1/提取管2）

消毒棉棒/收集袋

新型冠狀病毒抗原檢測試劑
(SARS-Cov-2) Antigen Test Kit
Saliva

產品表現

靈敏度 96.4% ｜特異性 99.8% ｜高精準度

產品特點

簡單易用
快速自我檢測，15分鐘即驗即知
可檢測新冠病毒、Omicron及Delta變種病毒
對無症狀感染及早期感染檢測有高精準度
技術由英國大學研發
有效期24個月

國際機構認證

歐盟認證CE1434
德國Germany BfArM Self Test List and Professional Use Test List
法國 French ANSM Self test and Professional use test registration
意大利 Italy Self Test Registration
瑞士 Switzerland Self Test Registration

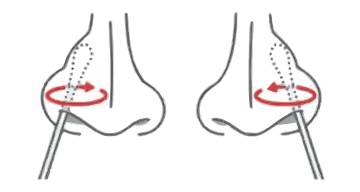
英國政府驗證

英國公共衛生部(PHE) 聯同牛津大學獨立評估了衛生及社會關懷部 (DHSC) 推薦的140 款快速抗原檢測試劑。 只有少數能通過3A期，我們的試劑甚至通過了3B期。這意味著我們的測試在多種病毒的情況下具有非常高的準確性，並且能夠檢測到無症狀感染的患者和不同新的變種病毒。

產品使用說明

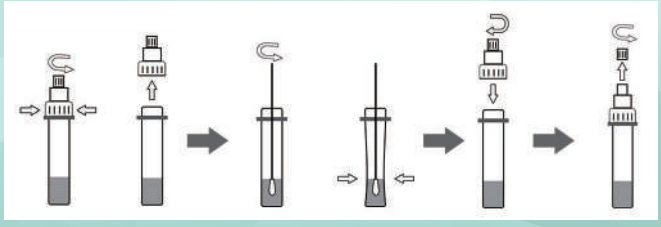
使用教學影片

1. 採集樣本

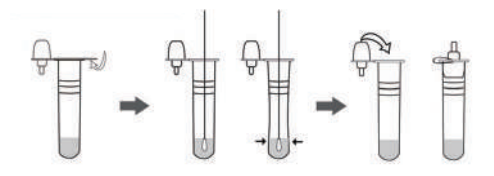


把棉棒插入鼻腔，棉棒尖端應插入2厘米；把棉捧在鼻腔內側轉動最少5個圈。使用相同的棉棒，對另一個鼻腔重複相同過程，以確保收集到足夠數量的樣本。

2. 準備樣本



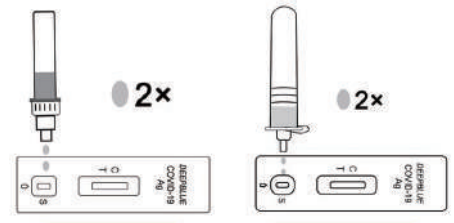
提取管1



提取管2

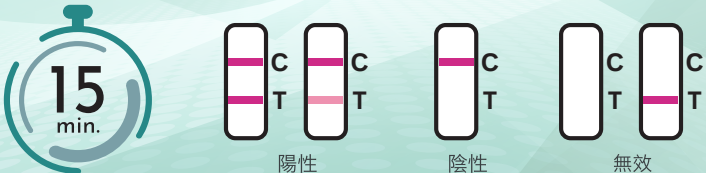
將拭子標本放入提取管中，轉動拭子約10秒，將拭子頭壓在管壁上3次，使拭子中的抗原釋放。將噴嘴牢牢按在提管上。

3. 測試



垂直握住提取管，將兩滴測試樣品加入加樣孔 (S) 中, 並開始計時。

4. 讀取測試結果



於15分鐘讀取結果，並於30分鐘內讀取，否則結果失效。

Bundesinstitut
für Arzneimittel
und Medizinprodukte

Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2

die Gegenstand des Anspruchs nach §1 Satz 1 Coronavirus-Testverordnung (TestV) sind („Selbsttests")

Allgemeine Hinweise

anhui | Los | Aktionen

Nach 'anhui' suchen

			Hersteller		Europäischer Be
Test-ID	Name des Tests	Evaluieru... PEI	Name	Land	Name
AT1288/21	COVID-19 (SARS-CoV-2) Antigentestkit (kolloidales Gold) - Speichel	Ja	ANHUI DEEPBLUE MEDICAL TEC...	CN	Luxus Lebenswelt GmbH
AT1190/21	COVID-19 (SARS-CoV-2) Antigentestkit (kolloidales Gold)	Ja	ANHUI DEEPBLUE MEDICAL TEC...	CN	Luxus Lebenswelt GmbH

1 Zeilen ausgewählt

Germany BfArM Self Test List

			Hersteller	
Name des Tests	Evaluieru... PEI	Name	Land	
COVID-19 (SARS-CoV-2) Antigentestkit (kolloidales Gold)	Ja	ANHUI DEEPBLUE MEDICAL TEC...	CN	
COVID-19 (SARS-CoV-2) Antigentestkit (kolloidales Gold) - Speichel	Ja	ANHUI DEEPBLUE MEDICAL TEC...	CN	

Passed the PEI evaluation.

Hersteller		Europäischer Bevollmächtigter			Sensitivität		Spezifität	
	Land	Name	Land	Probennahme	%	95%iges Vertrauensin...	%	95%iges Vertrauensin...
PBLUE MEDICAL TEC...	CN	Luxus Lebenswelt GmbH	DE	nasal	96,40	90,8 - 98,2	99,80	94,4 - 99,9
PBLUE MEDICAL TEC...	CN	Luxus Lebenswelt GmbH	DE	Speichel	98,70	92,33 - 99,07	99,90	98,17 - 100

Performance：
Sensitivity: 98.7% (95% CI: 92.33% - 99.07%)
Specificity: >99.9% (95% CI: 98.17% - 100%)

CERTIFICATE

EC Certificate No. 1434-IVDD-484/2021

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Anhui Deepblue Medical Technology Co., Ltd.
4th Floor, D-1#Zone, Pearl Industrial Park, 106 Innovation Avenue, High-Tech Development Zone, 230088 Hefei, Anhui, China

in vitro diagnostic medical devices
for self-testing

COVID-19 (SARS-CoV-2) Antigen Test Kit

(Colloidal Gold) – Saliva

The list of medical devices covered by this certificate is provided in the annex 1

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 10.11.2021 to 27.05.2024

The date of issue of the Certificate: 10.11.2021

The date of the first issue of the Certificate: 10.11.2021

CE 1434

Issued under the Contract No. MD-113/2021
Application No: 230/2021
Certificate bears the qualified signature.
Warsaw, 10.11.2021
Module A1

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.11.10 16:15:24 +01'00'

Vice-President

ANNEX TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-484/2021

List of medical devices covered by the certificate:

DEEPBLUE, ShenLanTest, Highbluetest, NewBluetest, Quicklyblue

REF: SL030101SST-1, SL030101SST-2, SL030101SST-3, SL030101SST-4, SL030101SST-5, SL030101SST-6, SL030101SST-7, SL030101SST-8, SL030101SST-9, SL030101SST-10, SL030101SST-11, SL030101SST-12, SL030101SST-13, SL030101SST-14, SL030101SST-15, SL030101SST-16, SL030101SST-17, SL030101SST-18, SL030101SST-19, SL030101SST-20, SL030101SST-21, SL030101SST-22, SL030101SST-23, SL030101SST-24, SL030101SST-25

CE 1434

Issued under the Contract No. MD-113/2021
Application No: 230/2021
Certificate bears the qualified signature.
Warsaw, 10/11/2021

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.11.10 16:16:26 +01'00'

Vice-President

www.dbluemedical.com

DECLARATION OF CONFORMITY

MANUFACTURER:	ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD. 4th Floor,D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue, High-Tech Development Zone , 230088 Hefei, Anhui, People's Republic of China
EUROPEAN REPRESENTATIVE:	Luxus Lebenswelt GmbH Kochstr. 1, 47877, Willich, Germany
PRODUCT:	COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) -Saliva
Models:	SEE ATTACHMENT
REF:	SEE ATTACHMENT
CLASSIFICATION:	SELF-TESTING
EDMA CODE:	15 70 90 90 00

CONFORMITY ASSESSMENT ROUTE: Following the procedure relating to the EC Declaration of Conformity set out in Annex III Section 6 of Directive 98/79/EC.

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.
THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED:	EN ISO 13485:2016 EN ISO 18113-1:2011, EN ISO 18113-4:2011, EN 13612: 2002/AC:2002, EN ISO 23640:2015, EN 13641: 2002, EN ISO 15223-1: 2016, EN 13975:2003, EN 13532:2002, EN ISO 14971:2012.
NOTIFIED BODY:	Polish Center for Testing and Certification 469 Puławska Street,02-844 Warsaw,Poland
(EN) CERTIFICATE(S):	1434-IVDD-484/2021
START OF CE-MARKING:	2021-11-10
PLACE, DATE OF ISSUE:	HEFEI, 2021-11-12

CE 1434

SIGNATURE: **CHEN FENGLING**

GENERAL MANAGER

www.dbluemedical.com

DECLARATION OF CONFORMITY
ATTACHMENT

DEEPBLUE, ShenLanTest, Highbluetest, NewBluetest, Quicklyblue

Specification	REF
1 piece per box	SL030101SST-1
2 pieces per box	SL030101SST-2
3 pieces per box	SL030101SST-3
4 pieces per box	SL030101SST-4
5 pieces per box	SL030101SST-5
6 pieces per box	SL030101SST-6
7 pieces per box	SL030101SST-7
8 pieces per box	SL030101SST-8
9 pieces per box	SL030101SST-9
10 pieces per box	SL030101SST-10
11 pieces per box	SL030101SST-11
12 pieces per box	SL030101SST-12
13 pieces per box	SL030101SST-13
14 pieces per box	SL030101SST-14
15 pieces per box	SL030101SST-15
16 pieces per box	SL030101SST-16
17 pieces per box	SL030101SST-17
18 pieces per box	SL030101SST-18
19 pieces per box	SL030101SST-19
20 pieces per box	SL030101SST-20
21 pieces per box	SL030101SST-21
22 pieces per box	SL030101SST-22
23 pieces per box	SL030101SST-23
24 pieces per box	SL030101SST-24
25 pieces per box	SL030101SST-25

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 003706 0001 Rev. 01

Holder of Certificate: **ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.**
4th Floor, D-1# Zone
Pearl Industrial Park
106 Innovation Avenue, High-Tech Development Zone
230088 Hefei, Anhui
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagents by Colloidal Gold and Enzyme Chemical Reaction Method, Medical Ultrasonic Couplant, Acetowhite Solution, Epithelial Tissue Staining Solution, Rapid Test for Vaginitis(Polyamines) and Cell Preservation Solution**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 003706 0001 Rev. 01

Report No.: SH21130301

Valid from: 2021-06-22
Valid until: 2024-06-21

Date, 2021-06-16

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 003706 0001 Rev. 01

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.
4th Floor, D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue, High-Tech Development Zone, 230088 Hefei, Anhui, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ISO9001 certification

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 00121Q310783R0M/3400

We hereby certify that

ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO., LTD.

Unified Social Credit Code: 913401005501903714

4th Floor, D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue, High-Tech Development Zone, Hefei City, AnHui Province, P.R.China

by reason of its

Quality Management System

has been awarded this certificate for compliance with the standard

GB/T 19001-2016 / ISO 9001:2015

The Quality Management System Applies in the following area:

Colloidal Gold and Enzymatic Chemical Reaction Method in Vitro Diagnostic Reagents, Medical Ultrasound Coupling Agent, Epithelial Tissue Staining Solution, Vaginitis Rapid detection Kit (Polyamine Method), Cell Preservation Solution, Virus Sampling Tube, Medical Ice Cap and Wound Dressing within the Scope of Qualification's Development and Production

Certified since: November 11, 2021 **Valid from:** November 11, 2021 **Valid until:** November 10, 2024

After a surveillance cycle, the certificate is valid only when used together with an Acceptance Notice of Surveillance Audit issued by CQC.
Please access www.cqc.com.cn for checking validity of the certificate.
This certificate and its relevant information can query in the website of Certification and Accreditation Administration of the People's Republic of China (www.cnca.gov.cn).

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

CNAS 中国认可 国际互认 管理体系 MANAGEMENT SYSTEM CNAS C001-M

Signed by: Xie ZhaoXu

IQNet Partner of THE INTERNATIONAL CERTIFICATION NETWORK

CHINA QUALITY CERTIFICATION CENTRE 中国质量认证中心

CHINA QUALITY CERTIFICATION CENTRE

Section 9, No.188, Nansihuan(the South Fourth Ring Road) Xilu(West Road), Beijing 100070,China
http://www.cqc.com.cn

A 0027986

2021年版